

**HL7 SPL Working Group Process Communication Forum Telecon
Wednesday, October 1, 2008**

Agenda:

- Update from HL7 meeting (SPL ballot)
- Sub-team updates
 - OTC
 - ER/DL
 - Biologics
 - Generics
 - Other
- SPL wiki update <http://spl-work-group.wikispaces.com/>
- Upcoming meetings
- General updates
- AOB

Meeting Minutes:

Update from HL7 (SPL ballot)

The one outstanding item from the May ballot was approved at the September HL7 session. The schema did not require any changes. Some discussion about the concept of a Common Product Model, to provide a unified description of products among areas of Patient Safety, Pharmacy and ICSR.

Subteam Updates

OTC Subteam:

Leads: Paula Markert Paula.T.Markert@gsk.com
Devon Morgan Devon.Morgan@perrigo.com

Comments on the Draft Guidance were submitted to the FDA. A Q&A document is under development. Meetings are on alternate Mondays; check the <http://spl-work-group.wikispaces.com> page for details and minutes from prior meetings.

ER/DL Subteam:

Lead: Michael Fahmy Michael.fahmy@bms.com

A couple of sponsors have submitted SPL via the pilot e-list system. Individual sponsors are setting up time directly with D&B to discuss individual DUNS number concerns (non-active DUNS numbers, names and addresses with errors). Process flows and Q&A are being drafted for use on the WIKI. Lessons learned by individual sponsors are being turned into nuggets of useful information all the time. The team is looking into ways to walk through a product's process flow, to highlight the types of SPL information needed and create SPL examples.

Biologics Subteam:

Lead: Terry Brunone theresa.m.brunone@gsk.com

Generics Subteam:

Lead: Virginia Hogan Virginia.Hogan@tevausa.com

Comments from the subteam are being submitted via the GPhA.
Process flow and Q&As are under construction, for posting on the SPL Working Group WIKI. This group meets on alternating Mondays (opposite from the OTC team)

FDA Consultation on SPL:

For any specific questions about SPL, or if you want to set up a meeting to discuss your organization's specific Establishment Registration and/or Drug Listing SPL questions, send an e-mail to spl@fda.hhs.gov with your contact details.

WIKI-links:

R3 and R4 Process Flow Diagram at <http://spl-work-group.wikispaces.com/Submissions+Flow+Chart+for+r3+and+r4>

Training opportunities: <http://spl-work-group.wikispaces.com/Training>

Process Team minutes:

Our next Process Team meeting: October 15, 2008 1:00 – 2:30

Check out the SPL Working Group WIKI @:
<http://spl-work-group.wikispaces.com>